

EXHIBIT B

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MONTANA
MISSOULA DIVISION

UNITED STATES OF AMERICA,)	CR 05-07-M-DWM
)	
Plaintiff,)	
)	
vs.)	ORDER
)	
W. R. GRACE, ALAN R. STRINGER,)	
HENRY A. ESCHENBACH, JACK W.)	
WOLTER, WILLIAM J. McCAIG,)	
ROBERT J. BETTACCHI, O. MARIO)	
FAVORITO, ROBERT C. WALSH,)	
)	
Defendants.)	
)	

I. Introduction

Defendants W.R. Grace and Co., a Connecticut corporation ("Grace"), and current and former Grace employees Alan R. Stringer, Henry A. Eschenbach, Jack W. Wolter, William J. McCaig, Robert J. Bettacchi, O. Mario Favorito and Robert C. Walsh, are charged by a ten-count Indictment with crimes arising from Grace's operation of a vermiculite mine near Libby, Montana (the "Libby Mine"). The Defendants are charged with conspiracy to violate the Clean Air Act and to defraud the United States in violation of 18 U.S.C. § 371 (Count I); violation of the Clean

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Air Act, 42 U.S.C. § 7413(c)(5)(A) (Counts II, III and IV); wire fraud in violation of 18 U.S.C. §§ 1343, 2 (Counts V and VI); and Obstruction of Justice in violation of 18 U.S.C. §§ 1505, 2 (Counts VII, VIII, IX and X). The charges relate to the Defendants' alleged role in the release and distribution throughout the Libby area of asbestos contaminated vermiculite.

Before the Court is defendant Grace's motion, filed on behalf of all defendants, to compel production of medical records in the government's possession pursuant to Rule 16(a)(1)(E) and (F), Fed. R. Crim. P. The Defendants ask the Court to order production of nearly 1,200 unredacted sets of medical records which Defendants allege are the basis for the claim in the Indictment that "approximately 1,200 residents of the Libby, Montana area have been identified as having asbestos related pleural abnormalities as a result of being exposed to tremolite asbestos produced by W.R. GRACE at the Libby Mine." Indictment, ¶ 57. The government contends that it is obligated to provide only those medical records pertaining to witnesses the prosecution intends to call at trial. The government further insists that it be permitted to redact the records to remove identifying information as well as any medical information that is unrelated to the victims' asbestos-related medical problems. The government has filed a motion for a protective order, arguing that the victim witnesses' privacy rights require redaction of

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the records prior to disclosure.¹

II. Factual Background

Following the Environmental Protection Agency's (EPA) identification of a potential hazardous waste emergency in Libby, Montana in 1999, the Agency for Toxic Substances and Disease Registry (ATSDR), an agency of the Department of Health and Human Services (DHHS), began an investigation into potential adverse health effects from exposure to asbestos contaminated vermiculite. The investigation included a medical testing study in which 6,668 participants who had lived, worked or played in Libby for a period of at least six months prior to December 31, 1990 received chest x-rays. The study revealed pleural abnormalities in 17.8 percent of those tested, or 1,186 participants. The United States relied on these findings in alleging the following at Paragraph 57 of the Indictment: "To date, approximately 1,200 residents of the Libby, Montana area have been identified as having asbestos related pleural abnormalities as a result of being exposed to tremolite asbestos produced by W.R. GRACE at the Libby Mine. Of this group, 70 percent are not former employees at the Libby Mine."

According to the government, the medical records of the

¹The Defendants' response brief in opposition to the government's motion (dkt #186) fails to comply with Local Rule 10.1(b) in that it is uses less than a 12 point font. Defendants have used impermissibly small fonts in other briefs as well. The parties are reminded to adhere to the Local Rules lest they be subject to sanctions.

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participants in the Libby study are not and never have been in the prosecution's possession, but are instead maintained by DHHS. The government has declared that it does not intend to use the 1,186 medical records at trial, but will present the medical records of the prosecution's testifying victim witnesses, at this point numbering sixteen. The Scheduling Order required that government to produce all materials discoverable under Rule 16, Fed. R. Crim. P., as well as other materials specified in Paragraph 5 of the Scheduling Order, no later than April 29, 2005. To date, the government has not disclosed the complete medical records of any of its victim witnesses.

III. Analysis

A. Availability of Medical Records Under Fed. R. Crim. P. 16

1. The Prosecution's Obligations Under Rule 16

Rule 16(a)(1)(E) provides:

Upon a defendant's request, the government must permit the defendant to inspect and to copy or photograph books, papers, documents, data, photographs, tangible objects, buildings or places, or copies or portions of any of these items, if the item is within the government's possession, custody, or control and:

(i) the item is material to preparing the defense;

(ii) the government intends to use the item in its case-in-chief at trial; or

(iii) the item was obtained from or belongs to the defendant.

In the event a defendant seeks discovery under Rule 16(a)(1)(E)(i) on the ground that the information sought is

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material to the preparing the defense, the defendant must make a threshold showing of materiality. United States v. Santiago, 46 F.3d 885, 894 (9th Cir. 1995). Such a showing "requires a presentation of 'facts which would tend to show that the Government is in possession of information helpful to the defense.'" Id. (quoting United States v. Mandel, 914 F.2d 1215, 1219 (9th Cir. 1990)). "Neither a general description of the information sought nor conclusory allegations of materiality suffice." Id. "Requests under Rule 16 must be sufficiently clear to inform the prosecution about what is sought." United States v. McVeigh, 954 F.Supp. 1441, 1450 (D.Colo. 1997).²

2. Does Rule 16 Require Production of Medical Records?

a. Medical Records of Testifying Victim Witnesses
Currently Held By the Prosecution

There is no question that the medical records of testifying victim witnesses are discoverable and must be produced under Rule 16(a)(1)(E). These records are material to the preparation of the defense under Rule 16(a)(1)(E)(i) and the prosecution intends to use them in its case-in-chief at trial, making them discoverable under Rule 16(a)(1)(E)(ii) as well. Moreover, the government does not dispute that the records are in the

²I have fully fleshed out the margins of discovery in a separate order filed contemporaneously with this one. That discussion will not be repeated here. See Order dated November 23, 2005, resolving Grace's Motion for Material and Exculpatory Information in the Possession of Government Agencies and the individual Defendants' Motion for Production of Brady Materials.

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possession of the prosecution. The only issue with regard to these records is whether the victim witnesses' privacy rights require the Court to place restrictions on the production in the form of redaction of sensitive material, issuance of a protective order, or both.

b. Medical Records of ATSDR Study Subjects Currently Held By DHHS

The medical records underlying the ATSDR study are discoverable if (1) they are material to preparing the defense or will be used in the government's case-in-chief and (2) they are in the government's possession, custody or control as defined by the "knowledge and access" test. See Rule 16(a)(1)(E), Fed. R. Crim. P.

The Defendants argue that the records are material, i.e. that they will be helpful to the defense, because they may be used by the Defendants to undermine various charges in the Indictment. For example, the Defendants contend that the records will show that a significant amount of asbestos-related disease in the Libby area was caused by exposure to asbestos that occurred prior to the period of the conspiracy alleged in the Indictment. The Defendants also intend to use the records to show that the Indictment overstates the adverse health effects resulting from the overt acts charged in the Indictment. This they plan to do by demonstrating that the 1,186 ATSDR study participants identified as having "asbestos related pleural

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abnormalities" have not been diagnosed with any asbestos-related medical problem. The Defendants note that the ATSDR survey was a screening study intended to identify individuals who should, because of abnormalities found during the study, seek additional medical testing to determine whether they have an asbestos-related illness.

The Defendants have met their burden of showing that the medical records underlying the ATSDR study are material for purposes of Rule 16(a)(1)(E)(i). The government has chosen to include in the Indictment an allegation that nearly 1,200 former and current Libby residents suffer from pleural abnormalities caused by asbestos exposure, and has indicated that it will rely on the ATSDR study and related expert testimony to prove its allegations of risk of harm and the attendant health effects of asbestos exposure. Any information that might allow the Defendants to assess the validity of that study is helpful to the defense and therefore material. Moreover, because the government appears to intend to rely on the ATSDR study in its case-in-chief, the records underlying that study are discoverable under Rule 16(a)(1)(E)(ii). Considerations of fairness and due process require that the Defendants not be forced to defend against a serious allegation of widespread health problems caused by their conduct without also having access to the data upon which the allegation is based.

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Rule 16 also requires that the Defendants show that the medical records underlying the ATSDR study are within the government's possession, custody and control as defined by the "knowledge and access" test. Because there is no question that the prosecution is aware of the existence of the medical records underlying the ATSDR study, the Court's inquiry focuses on whether the prosecution has access to the records underlying the study. Just because the prosecution has requested and received some information from ATSDR, including the final screening study report, does not mean that the prosecution has access to the medical data underlying the study.

An assessment of the prosecution's access to the medical records must acknowledge that the records are confidential health information the disclosure of which is regulated by federal statutes. Two statutes limit the disclosure by government agencies of confidential medical information. The Health Insurance Portability and Accountability Act ("HIPAA"), Pub. L. No. 104-191, places limitations on the disclosure of medical records held by a health plan, a health care clearinghouse, or a health care provider making certain electronic transmissions. 42 U.S.C. § 1320d-1(a). A "health care clearinghouse" is defined as "a public or private entity that processes or facilitates the processing of nonstandard data elements of health information into standard data elements." 42 U.S.C. § 1320d(2). Although it

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is not entirely clear that ATSDR or DHHS meet the definition of a "health care clearinghouse" as defined by HIPAA, I assume that HIPAA applies to the agency holding the medical records.

The rules governing disclosure under HIPAA of information to be used in a judicial proceeding are set forth at 45 C.F.R. § 164.512(e) and provide, in relevant part, as follows:

(1) Permitted disclosures. A covered entity may disclose protected health information in the course of any judicial or administrative proceeding:

(i) In response to an order of a court or administrative tribunal, provided that the covered entity discloses only the protected health information expressly authorized by such order; or

(ii) In response to a subpoena, discovery request, or other lawful process, that is not accompanied by an order of a court or administrative tribunal, if:

(A) The covered entity receives satisfactory assurance, as described in paragraph (e)(1)(iii) of this section, from the party seeking the information that reasonable efforts have been made by such party to ensure that the individual who is the subject of the protected health information that has been requested has been given notice of the request; or

(B) The covered entity receives satisfactory assurance, as described in paragraph (e)(1)(iv) of this section, from the party seeking the information that reasonable efforts have been made by such party to secure a qualified protective order that meets the requirements of paragraph (e)(1)(v) of this section.

(iv) For the purposes of paragraph (e)(1)(ii)(B) of this section, a covered entity receives satisfactory assurances from a party seeking protected health information, if the covered entity receives from such party a written statement and accompanying documentation demonstrating that:

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(A) The parties to the dispute giving rise to the request for information have agreed to a qualified protective order and have presented it to the court or administrative tribunal with jurisdiction over the dispute; or

(B) The party seeking the protected health information has requested a qualified protective order from such court or administrative tribunal.

(v) For purposes of paragraph (e)(1) of this section, a qualified protective order means, with respect to protected health information requested under paragraph (e)(1)(ii) of this section, an order of a court or of an administrative tribunal or a stipulation by the parties to the litigation or administrative proceeding that:

(A) Prohibits the parties from using or disclosing the protected health information for any purpose other than the litigation or proceeding for which such information was requested; and

(B) Requires the return to the covered entity or destruction of the protected health information (including all copies made) at the end of the litigation or proceeding.

HIPAA allows the agencies involved here to disclose information to the prosecution if the prosecution subpoenas the information or the information sought is responsive to a discovery request, provided the prosecution has either entered a stipulated protective order with the defense or has requested a protective order from the court having jurisdiction over the case. Because the prosecution need only request a qualified protective order to receive information covered by HIPAA, that statute does not present a barrier to the prosecution's access to the medical records underlying the ATSDR study and currently held by DHHS.

The other applicable statute is the Privacy Act, 5 U.S.C. §

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552a. The relevant portions of the Privacy Act provide, at 5

U.S.C. § 552a(b),

No agency shall disclose any record which is contained in a system of records by any means of communication to any person, or to another agency, except pursuant to a written request by, or with the prior written consent of, the individual to whom the record pertains, unless disclosure of the record would be-

.....
(7) to another agency or to an instrumentality of any governmental jurisdiction within or under the control of the United States for a civil or criminal law enforcement activity if the activity is authorized by law, and if the head of the agency or instrumentality has made a written request to the agency which maintains the record specifying the particular portion desired and the law enforcement activity for which the record is sought; [or]

.....
(11) pursuant to the order of a court of competent jurisdiction.

The Privacy Act authorizes an agency to disclose medical records to "an instrumentality of any governmental jurisdiction," such as the United States Attorney's Office, for the purpose of criminal law enforcement activity, provided that the United States Attorney makes a written request to the agency specifying the information desired and the purpose for which it is sought. Because it appears that federal agency records covered by the Privacy Act are available to federal prosecutors upon written request, the act does not impede the prosecution's access to agency files in any meaningful way.

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There is no statutory impediment to the prosecution's access to the medical data underlying the ATSDR study. What remains is a factual inquiry into whether the prosecution has access to DHHS files. The prosecution concedes that it has requested and received information held by ATSDR, including the asbestos screening study conducted in Libby. ATSDR is an agency within DHHS, although the prosecution has not been clear whether the medical records underlying the screening study are held by ATSDR or are kept elsewhere within DHHS.

The outcome of this inquiry does not turn on whether ATSDR or some other entity within DHHS has actual custody of the underlying medical records. The prosecution was able to obtain some files from ATSDR, including the screening study. There is no reason to assume that the prosecution could not gain access to the underlying medical data had it wanted the information. From the prosecution's perspective, however, there is little incentive to request the medical information upon which the study is based. The study itself provides the government with the information useful to the prosecution, i.e. the conclusion that a significant number of Libby residents have shown pleural abnormalities. The data underlying the study does nothing to add to the strength of the government's allegation of widespread sickness; rather, the utility of the underlying data lies in the possibility that the information might suggest avenues for the defense to undermine or

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clarify the findings of the ATSDR study and to limit its harmful impact. This information is potentially useful to the defense, but one can see why it would be of little interest to the prosecution. For this reason, an assessment of the prosecution's access must be based not on what the prosecution has requested or from whom, but rather on what the prosecution appears able to obtain, regardless of attempt.

The question is a close one. The court in United States v. Bryan, 868 F.2d 1032, 1036 (9th Cir. 1989), described the competing considerations, forbidding prosecutors from employing "a mechanical definition of 'government' that would deny to the defendant documents accessible to the prosecution," while also stating, "[A] prosecutor need not comb the files of every federal agency which might have documents regarding the defendant in order to fulfill his or her obligations under [Rule 16(a)(1)(E)]." Weighing those considerations in this case, I find that the scales tip in favor of requiring disclosure. There is a strong likelihood that the prosecution would deny the Defendants documents to which the prosecution itself could have access if it desired. Moreover, these documents are probably of greater utility to the defense than to the prosecution. Ordering disclosure in this instance is a far cry from forcing the prosecution to "comb the files of every federal agency," because the prosecution has placed the information at issue by basing

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allegations in the indictment on the ATSDR study and planning to introduce the study's findings at trial. These considerations warrant a finding that the medical records supporting the ATSDR study are within the government's possession under the "knowledge and access" test and that the other elements of Rule 16(a)(1)(E) are satisfied as to require disclosure of the medical records, subject to restrictions necessary to protect that study participants' privacy rights.

B. What Precautions Are Necessary to Protect Confidential Information?

1. Medical Records of Testifying Victim Witnesses

The government states that it will disclose the medical records of testifying victim witnesses, but insists that disclosure be subject to a strict protective order and that the government be allowed to unilaterally redact all identifying information and all medical information it deems "wholly unrelated" to the illnesses at issue in this case.¹ The government contends that such steps are mandated by the relevant statutes and case law.

The defense is willing to enter a strict protective order, but objects to the prosecution's plan to withhold identifying

¹The government proposes to inform the Defendants as to which set of medical records belongs to each testifying witness 30 days before trial. The government offers no argument in support of this procedure except to state that it is intended to protect the testifying witnesses' privacy. That arbitrary limit on disclosure is unreasonable.

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information and redact portions of the medical records. The Defendants argue that the government is not qualified to make medical determinations as to what information is "wholly unrelated" to the illnesses at issue in the case, and that the Defendants are entitled to have their experts review the complete medical records of the testifying witnesses for potentially useful information.

In addition to the privacy statutes cited above, Ninth Circuit has recognized a constitutionally protected interest in avoiding disclosure of medical information. Tuscan Women's Clinic v. Eden, 379 F.3d 531, 551 (9th Cir. 2004) (citation omitted). "Like the right to decide whether to terminate a pregnancy, the right to informational privacy is not absolute; rather, it is a conditional right which may be infringed upon a showing of proper governmental interest." Id (citation omitted).

We balance the following factors to determine whether the governmental interest in obtaining information outweighs the individual's privacy interest: (1) the type of information requested, (2) the potential for harm in any subsequent non-consensual disclosure, (3) the adequacy of safeguards to prevent unauthorized disclosure, (4) the degree of need for access, and (5) whether there is an express statutory mandate, articulated public policy, or other recognizable public interest militating toward access.

Id (citation omitted).

Application of those factors in this case strongly favors an order requiring the government to disclose the medical records of testifying witnesses in their entirety, subject to a strong

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protective order. The type of information requested is sensitive, and the risk of harm from non-consensual disclosure is great, but the remaining three factors mandate full disclosure in this case. The Court is in a position to issue a strict protective order supported by threat of sanctions, which is a substantial safeguard against unauthorized disclosure.

Considering factors (4) and (5) together, there is a high degree of need for access and a public policy (i.e., the Rules of Discovery) that favors access. Due process requires that defendants confronted by victim witnesses have an opportunity to inspect the medical records upon which the witnesses base their claims of injury, and that the inspection take place without the arbitrary removal of portions of the records by the prosecution.

The victim witnesses have already disclosed confidential medical information to the government. By agreeing to serve as witnesses in a criminal case, the testifying witnesses must assume that their medical information will become known to the defense. In most cases dealing with informational privacy, an individual is seeking to block disclosure of private information to the government. See, e.g., Eden, 379 F.3d 531 (patients seeking abortions challenge a state law requiring clinics to provide reports, including medical records, to state agency); In re Crawford, 194 F.3d 954 (9th Cir. 1999) (bankruptcy petition preparer challenging federal law requiring inclusion of

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preparer's Social Security number on petition). Here, the testifying witnesses have already disclosed their private information to the government, and the government is in turn asserting the witnesses' privacy rights as a basis for not disclosing information to the defense. There is no ground for the prosecution's contention that disclosure of complete records to the Defendants subject to a protective order poses any greater risk to privacy than disclosure of the same records to the government.

Neither the testifying witnesses' privacy rights nor the applicable statutes (HIPAA and the Privacy Act, both of which allow disclosure subject to a protective order) require the redaction of medical records before disclosure. The government must produce the records in their entirety, subject to the strict protective order set forth below in Part IV. The records will include the witnesses' names, although the government may redact sensitive identifying information such as addresses, contact information, insurance information and Social Security numbers.

2. Medical Records Underlying the ATSDR Study

The medical records underlying the ATSDR study present two different considerations that may warrant greater or less protection upon production. First, the medical records underlying the ATSDR study are not complete medical records, but instead consist only of medical histories provided and tests

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performed in relation to the study. This decreases the likelihood that any portion of the information contained in the records will be unrelated to asbestos exposure. Second, the identities of the participants in the study are not as important to the defense as are the identities of the testifying witnesses. As it relates to the testifying witnesses, the Defendants will be looking to rebut individual claims of injury. By contrast, with regard to the study participants' information, the Defendants will seek to undermine the broad conclusions of the study; there is no apparent utility to knowing the names of the participants in that case.

Accordingly, in the interest of the study participants' privacy rights, I will allow the prosecution to redact the names of the study participants prior to disclosing the medical information underlying the ATSDR study.⁴ Disclosure will nonetheless be subject to the strict protective order set forth below.

IV. Order

Based on the foregoing, IT IS HEREBY ORDERED that the Defendants' motion to compel production of medical records (dkt #178) is GRANTED and the government's motion for a protective

⁴To the extent such information is contained in the ATSDR records, the government may also redact sensitive identifying information such as addresses, contact information, insurance information and Social Security numbers.

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order (dkt #202) is GRANTED in PART and DENIED in part as set forth herein. Production shall be subject to the following protective order:

(1) The government will provide each defendants with a single copy of the complete medical records and related documents for each of the government's testifying victim witnesses (hereinafter "Witness Medical Records").

(2) The Witness Medical Records provided by the government will be redacted to remove sensitive identifying information such as addresses, contact information and Social Security numbers. The Witness Medical Records should not be otherwise redacted. With each set of records, the information provided should include the patient's name.

(3) No person or party may make copies of the Witness Medical Records provided by the government, nor are the defendants to exchange copies among themselves or their counsel. Defense counsel shall expressly advise every authorized person whom they have review the records as to this prohibition.

(4) Right to access the Witness Medical Records is limited to: (a) attorneys representing the defendants and the government in this action; (b) medical and scientific experts, whose review of that material is necessary for the presentation of defendants' or the government's case; (c) such law clerks, investigative agents, paralegals, and secretaries employed by defendants or the

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government's attorneys and agents, whose review of that material is required for the preparation and presentation of defendants' or the government's case; (d) the testifying witnesses or any representative they designate; and (e) the defendants.

(5) The Witness Medical Records shall be maintained by defense counsel in accordance herewith and shall be used by counsel solely and exclusively in connection with this case (including trial preparation, trial, and appeals or other related legal proceedings) and for no other purpose. Defense counsel shall expressly advise every authorized person whom they have review the records as to this limitation on lawful use.

(6) The Witness Medical Records shall be maintained by defense counsel in a locked file or cabinet at all times except when being actively utilized, and a copy of this Order shall be kept with the Witness Medical Records at all times.

(7) Within sixty (60) days after the conclusion of the trial, or if an appeal is taken, within sixty days following the return of the mandate to the District Court, defense counsel shall return to the prosecution the same set of Witness Medical Records as were provided by the prosecution, and shall maintain no portion of the Witness Medical Records in their own files. The government shall, in a timely manner, provide the Court with notice upon the return of complete sets of original Witness Medical Records by all defendants. In the event such return is

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delayed beyond the sixty-day deadline set forth in this paragraph, the government shall provide the Court with written notice of the nature of the delay.

(8) Upon certification to this Court of the receipt of all original sets of Witness Medical Records, the government shall promptly destroy all sets of records received from the defendants.

(9) The government will provide or make available for copying all information, including confidential medical information, underlying the ATSDR Study (hereinafter "ATSDR Study Records"). Prior to providing the ATSDR Study Records, the government shall remove all identifying information, including participants' names and all contact information, but shall not remove or redact any medical information. Paragraphs (4) and (5) of this Order apply with respect to the ATSDR Study Records.

(10) Failure or any party to comply with the terms of this Order will be punished to the full extent of the Locals Rules, the Federal Rules of Criminal Procedure, and the Court's inherent authority.

DATED this 23rd day of November, 2005.


DONALD W. MOLLOY, Chief Judge
United States District Court